

Serial No. 10/331,069

REMARKSStatus of the Claims

Claim 1-57 are pending in this application.

Claims 28-57 are withdrawn from consideration.

Claims 1-17 are currently under examination.

Claims 2-9 are cancelled.

Claims 1, 13, 18, and 21 are amended herein. No new matter is introduced.

Claim Rejections35 U.S.C. § 112, ¶1

The Examiner has rejected claims 1-27 under 35 U.S.C. §112, first paragraph, "because the specification, while being enabling for 2-amino-4,5-dimethylthiazole to inhibit advanced glycation endproduct (AGE), does not reasonably provide enablement for all pharmaceutical compositions of the formula in claim 1 to inhibit advanced glycation endproduct." Claim 1, as amended herein, is now limited to cosmetic and pharmaceutical compositions comprising 2-amino-4,5-dimethylthiazole, which the Examiner has acknowledged is enabled by the specification as filed. As such, this rejection is *moot*. This amendment is made solely to expedite allowance of claims directed to this currently preferred embodiment. However, Applicants reserve the right to address the merits of this rejection in the future, in this or any continuation or divisional applications.

35 U.S.C. §102 and §103

The Examiner has rejected claims 1-9, 13, 15-18, 21, and 23 as anticipated under §102(b) by U.S. Pub. 2002/0022622 ("Wagle"). The Examiner states that Wagle "meets the limitation of 2-amino-4,5-dimethylthiazole" in the case where "J is sulfur, R^a and R^b are alkyl and R^c is amino" in Formula I of Wagle's claim 1. Further, the Examiner has rejected claims 10-12, 14, 19-20, 22, and 24-27 under § 103 as obvious over Wagle in view of Gould (*Int. J. Pharmaceutics*, 33 (1986) 201-217), on which the Examiner relies as teaching "that hydrochloride is an FDA-approved commercially marketed salt." The Examiner note that Wagle does not teach "the weight percentages of the composition" but contends that "it is obvious to vary and/or optimize the amounts of 2-amino-4,5-dimethylthiazol[e] provided in the

Serial No. 10/331,069

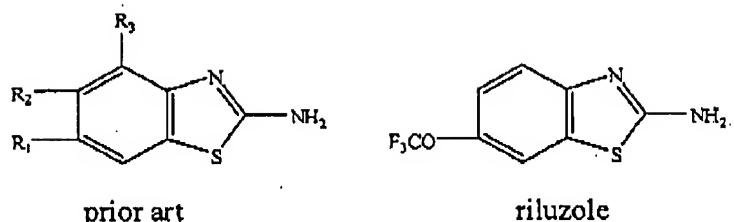
composition, according to the guidance provided by Wagle et al., to provide a composition having the desired properties such as the desired percentages that will effectively treat a disease or condition." Applicants traverse these rejections.

Wagle does not disclose 2-amino-4,5-dimethylthiazole. Wagle's claim 1, to which the Examiner refers, is comparable to the description in Wagle's specification at ¶¶ [0015]-[0046]. This genus embraces a potentially infinite number of species formed by selecting J, R^a, R^b and R^c and cannot constitute a legally sufficient disclosure of the species 2-amino-4,5-dimethylthiazole. See In re Petering, 301 F.2d 676, 681 (C.C.P.A. 1962). Further, while Wagle discloses several exemplary compounds at ¶¶ [0127]-[0194], including 2-aminothiazole ¶ [0138], 4,5-dimethylthiazole at ¶ [0128], 2-amino-5-methylthiazole at ¶ [0140], and 2-amino-4-methylthiazole at ¶ [0141], there is no identification of the presently claimed species 2-amino-4,5-dimethylthiazole. Moreover, in no case does Wagle exemplify any 2-aminothiazole derivative where both R^a and R^b constitute alkyl groups, let alone methyl groups. As such, Wagle may be said to lead one skilled in the art away from the particular species 2-amino-4,5-dimethylthiazole. Accordingly, Applicants submit that the currently amended claims fully distinguish over Wagle.

Further, Applicants submit that Wagle cannot anticipate the present claims because, by the Examiner's own reasoning, it is not enabling with respect to 2-amino-4,5-dimethylthiazole. In order to be anticipating, a prior art reference must be enabling so that the claimed subject matter may be made or used by one skilled in the art. See Impax Laboratories v. Aventis Pharmaceuticals, 468 F.3d. 1366, 81 U.S.P.Q.2d 1001 (Fed. Cir. 2006). The Examiner has rejected Applicants' claim 1 under §112, first paragraph, as lacking enablement for any species within the disclosed genus except for 2-amino-4,5-dimethylthiazole, for which AGE inhibition and cleavage data is provided. Applicants note that Wagle provides no data with respect to any compound disclosed therein. It would appear anomalous that the Examiner finds Applicants' more limited genus, which is supported by data for an exemplary species, to lack enablement, whereas Wagle's broader genus is said to anticipate and thus necessarily be considered by the Examiner to be enabling.

Moreover, on similar facts the Federal Circuit held in the recent Impax case that a prior art reference which described the genus of benzothiazole compounds shown below did not describe, and thus did not enable the drug riluzole for treating ALS.

Serial No. 10/331,069



The Court noted that "riluzole is just one of hundreds of compounds included in formula I" of the prior art and stated that where "a reference discloses a class of compounds, *i.e.*, a genus, a person of ordinary skill in the art should be able to 'at once envisage each member of th[e] . . . class' for the individual compounds, *i.e.*, species, to be enabled" and "[i]f the members cannot be envisioned, the reference does not disclose the species and the reference is not enabling." Impax, 468 F.3d at 1383. The Court held that "with the large number of compounds included in formula I and no specific identification of riluzole," the prior art reference "does not disclose riluzole, and therefore, cannot enable treatment of ALS with riluzole." *Id.* Applicants submit that the present case presents a more clear cut case of lack of description and enablement than Impax, because here, rather than "hundreds of compounds" being embraced by the genus, there is effectively an infinite number of compounds.

Based on the foregoing, Applicants submit that the present claims are neither anticipated nor obvious because Wagle neither describes nor enables the presently claimed species.

Serial No. 10/331,069

CONCLUSION

Applicants respectfully submit that the instant application is in condition for allowance. Entry of the amendments and an action passing this case to issue is therefore respectfully requested. In the event that a telephone conference would facilitate examination of this application in any way, the Examiner is invited to contact the undersigned at the number provided.

Respectfully submitted,

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